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INVESTIGATION OF RISPERIDONE; CASE OF SELECTED PATIENTS FROM KENYA

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ABSTRACT

Risperidone is considered as an atypical antipsychotic. It is considered as an effective treatment of psychotic disorders in adults. However, our understanding of its usage among young individuals is limited. In this study, the objective was to identify the safety profile of Risperidone among young children. Methodology wise, the study was conducted among children of less than 5 years old who were treating behavioral problems associated with various childhood disorders. The study was conducted in a hospital in Nairobi, Kenya. Common childhood disorders were diagnosed using the Diagnostic and Statistical Manual (DSM IV) and those associated with disruptive behavioral problems. We used Clinical Global Impression- Severity (CGI-S) and Improvement (CGI-I) scales for symptoms severity and improvement respectively. We took informed consents from parents of the children and initiated Risperidone. The total of 12 patients were included in the study consist of PDD (n=4), PDD plus ADHD (n=2), PDD plus ADHD plus Intellectual disability (n=2), Cerebral Palsy with Epilepsy (n=2) and Global developmental delay (n=2). Baseline and end point CGI scores were 5-6 and 1-2 respectively. Baseline investigations such as lipid profile, fasting blood sugar levels, Electro cardiogram (ECG) were recorded and compared before and after initiation of risperidone. Dose range of risperidone was 0.5-2mg per day. Common side effects were sedation and weight gain in a few patients only. No life-threatening side effects were noted. Our conclusion is that risperidone is well tolerated even in children below 5 years of age over a period of 1 year with improvement in target symptoms.

Keywords: Young Children, Risperidone, Safety and Efficacy.

INTRODUCTION

Risperidone is a typical antipsychotic and its indications for usage among adults include acute case of mania in bipolar disorder, schizophrenia, persistent aggression, Alzheimer's disease, and conduct disorder. Previously, Risperidone was used for adults only, however, now it is started to use for youngsters such as age group of 5 years to 16 years especially after the approval of US FDA [1]. So far, it is found to be safe and effective among this age group. However, there is limited data available about administering it for youngsters less than 5 years of age.

MATERIAL AND METHODS

The study was based on a tertiary care hospital located in Nairobi, Kenya. The department of Psychiatry and Child neurology was the focus point of this study. All patients in this department were referred by outpatient department. We included those children who were diagnosed with Pervasive development disorder, ADHD, Intellectual disability, and Cerebral Palsy [2]. Common symptoms of these patients were out of control behavior, aggression, and irritability. We took informed consents from guardian/parents of these children whom we included in the study. Initially, we administered smaller dose and gradually increased its quantity. Side by side, we used Clinical Global Impression-severity (CGI-S) and improvement (CGI-I) [3] scales. We continued follows up for 4 weeks and continued assessed clinical improvement and side effects. For some cases, we continued follow up to 1 year. Other indicators including ECG, Lipid profile, fasting blood sugar, and base line weight were also monitored.

RESULTS

In this present study, there were total of 12 patients who were included in the study. Among these patients, 4 had pervasive developmental disorder; 2 had PDD plus attention deficit hyperactive disorder; 2 had PDD plus ADHD plus intellectual disability; 2 had Cerebral palsy with epilepsy; and 2 had Global developmental delay. Their baseline and end point CGI scores were 5-6 and 1-2 respectively. We started administering the risperidone dose from 0.25 to 0.5 mg. we gradually increased the dose in case of minimal or non-responsive to the lower doses. We administered dose increment among 10 patients out of total of 12 patients. We observed no side effects among 4 patients, and 2 patients showed abnormal weight gain.

Table 1: Shows base line and final assessment of weight and Fasting blood sugar level along with demographic details

Gender	Age in Years	Diagnosis Results	Weight – Pre Treatment	Weight- Post Treatment	FBS baseline	FBS after 1 year
Male	3	CP with Epilepsy	10	12	88	90
Male	5	CP with Epilepsy	12	13	76	87
Male	4	CP with Epilepsy	13	14	69	76
Male	4	CP with Epilepsy	14	15	70	75
Female	3	PDD with AHDD	12	12	78	79
Male	3	CP with Epilepsy	12	12.50	89	82
Male	4	PDD with ADHD	13	14	97	90
Male	5	CP with Epilepsy	14	15	91	89
Female	5	CP with Epilepsy	15	14	78	80
Male	5	PDD with AHDD	15	15	70	89
Male	4	PDD with AHDD	13	14	83	76
Male	3	CP with Epilepsy	12	12	85	89

No patient included in our study showed severe side effects such as extra pyramidal side effects (EPS). We conducted other measures such as Lipid profile and fasting blood sugar and found no significant increase in base line levels. normal fasting blood sugar levels were < 100mg/dl and normal Total Cholesterol levels were <300 mg/dl and normal Triglyceride levels < 150 mg/dl.

Table-2: Shows base line and final lipid profile, CGI scores along with drug side effects

Lipid Profile Baseline		Lipid Profile after 1 Year		Side Effects after 4 Weeks	Side Effects after 6 Months	Side Effects after 1 Year	CGI Score	CGI Score after 1 Year
TC	TG	TC	TG	No Effects	No Effects	No Effects	6	2
115	67	145	65	Sedation	Weight Gain	No Effects	6	2

123	69	154	61	No Effects	No Effects	No Effects	6	2
165	75	167	63	No Effects	No Effects	No Effects	5	1
134	63	167	67	No Effects	No Effects	No Effects	5	1
122	55	178	68	Sedation	Weight Gain	No Effects	6	1
116	60	162	54	Sedation	No Effects	No Effects	5	2
118	76	189	57	No Effects	No Effects	No Effects	6	2
123	71	152	51	No Effects	No Effects	No Effects	6	1
113	74	146	80	Sedation	Weight Gain	No Effects	6	1
121	70	148	78	No Effects	No Effects	No Effects	5	2
115	81	154	82	No Effects	No Effects	No Effects	5	2
126	72	151	84	No Effects	No Effects	No Effects	6	1

Discussion

Behavioral problems can lead to the developmental disorders and is a major problem these days. Common examples of behavioral problem include self-injurious behavior, hyperactivity, aggression, and irritability which are often associated with Pervasive developmental disorders, mental retardation, and ADHDs [4]. It is estimated that such behavior prevail among 4 to 9% of all children [5, 6]. The problem is that these behavioral problems interfere with rehabilitative efforts and pose severe challenges to parents, relatives, and other stakeholders such as educators and society [7]. It is recommended that in situation where behavioral problems interfere with daily activities, parents/guardian should seek pharmacological intervention. Typical Antipsychotics like haloperidol are commonly utilized, however, there risk of unwanted extra pyramidal symptoms is quite high. Atypical antipsychotics score over typicals in these side effects. Risperidone is also a solution for treating behavioral symptoms among adults. Most studies about its results are conducted among adults, and there is no such data of administering it among children less than 5 years of age [8]. Common behavioral problems among children can also be treated using the Risperidone as reports shows that it can help in overcoming these behavioral problems [9]. Here, it is important to mention that besides the medicine, the psychosocial intervention should be given priority for treating children behavioral problems [10]. Psychopharmacological intervention is required if symptoms causes significant distress to parents and other related individuals [11]. Based on this study, we reported that Risperidone can be used to treat effectively the disruptive behavior among preschool children. Our findings are matching with other studies findings which also reports similar findings. For example, study showed that Risperidone can be used for treatment of aggressive behavior in preschool children

[12]. Common diagnosis for which Risperidone is used includes disruptive behavior disorder, ADHD, ID, and PDD [10]. In our study, we administered the Risperidone among children who were less than 5 years of age. We found that among these children, the common side effects of the Risperidone are weight gain and sedation. Overall, we found that Risperidone can be used to treat behavioral problems along with other psycho-social support to children.

CONCLUSION

On study findings basis, our conclusion is that Risperidone is well tolerated among children below 5 years of age. We observed in improvement in targeted symptoms as observed by us and parents. The improvement is also associated with reduced family burden and improved quality of life.

Limitations

The study limitations included small sample size and hence we suggest a larger study in future which can be placebo-controlled investigation or double blind in nature.

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